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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/808,964      | 03/25/2004  | Xiang-Jin Meng       | AM100878-P1         | 7042             |

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Anne M. Rosenblum, Esq.  
163 Delaware Avenue - Suite 212  
Delmar, NY 12054

EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/808,964

Applicant(s)

MENG ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 15, 16 and 18-32 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 32 is/are allowed.
- 6) ☒ Claim(s) 4-10, 15, 16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on July 22, 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Stacy Chen, Group Art Unit 1648.

2. Applicant's amendment filed December 7, 2005 is acknowledged and entered. Claims 1-10, 15, 16 and 18-32 are pending. Claims 23-31 remain withdrawn from consideration, being drawn to non-elected subject matter. Claims 11-14 and 17 have been cancelled. Claims 1-10, 15, 16, 18-22 and 32 remain under examination.

### ***Oath/Declaration***

3. The oath or declaration filed August 16, 2004 is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to Xiang-Jin Meng's country of citizenship. While the alteration of citizenship was initialed, it was not dated, as required by 37 CFR 1.52(c).

### ***Response to Amendment***

4. The following rejections are withdrawn:

- The provisional double patenting rejection of claims 1-4, 6-10, 15(a-c), 18-22 and 32 as claiming the same invention as that of claims 1-9, 13(a-c), 14-18 and 25 of co-

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pending USSN 10/314,512, is withdrawn in view of Applicant's amendment to the claim(s) of the co-pending application.

- The rejection of claims 7 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirements (specifically the ATCC deposit PTA-3912), is withdrawn in view of the statement provided by the attorney of record that PTA-3912 has been deposited in the ATCC on 12/7/01 under the terms of the Budapest treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.
- The rejection of claims 15(a-c), 16 and 18-22 under 35 U.S.C. 112, first paragraph, because the specification fails to enable the full scope of the claims, is withdrawn. Previously, examiner Foley interpreted the claims to encompass methods of treating and protecting. However, as Applicant points out, the claims are limited to protection and do not encompass treatment. Further, claim 15(c), is limited to a chimeric porcine circovirus derived from a chimeric nucleic acid molecule of PCV1-2.
- The rejection of claim 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of Applicant's persuasive arguments. The specification clearly describes the claimed mutations (page 19, line 21 to page 20, line 2).
- The rejection of claims 1-3 and 32 under 35 U.S.C. 103(a) as unpatentable over Allan *et al.* (US 6,217,883) in view of Caggana *et al.* (*J. Virology*, 1993), Lustig *et al.* (*J. Virology*, 1988) and Mahé *et al.* (*J. Gen. Virology*, 2000), is withdrawn in view of

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Applicant's persuasive arguments. The combination of references lacks motivation to make chimeric PCV1-2 constructs. While Caggana *et al.* (*J. Virology*, 1993) and Lustig *et al.* teach chimeric constructs, the viruses used are not related to PCV types 1 and 2 in such a way that the instantly claimed chimeric constructs would be *prima facie* obvious.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(*New Rejection*) Claims 4-10, 15, 16 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 and dependent claims recite, "wherein the chimeric nucleic acid molecule has a nucleotide sequence set forth in SEQ ID NO: 2, its complementary strand", *etc.* It is unclear whether Applicant intends to claim the full-length SEQ ID NO: 2, because the language implies that fragments of SEQ ID NO: 2 could be encompassed. If Applicant intends to reference the entire SEQ ID NO: 2 (and a full-length complement), suggested language is, "wherein the chimeric nucleic acid molecule comprises the nucleotide sequence set forth in SEQ ID NO: 2, its complementary strand", *etc.* Clarification and/or correction is required to overcome this rejection.

Claim 10 recites, "wherein the cells containing the chimeric nucleic acid molecule are contained in or derived from a plasmid having ATCC Patent Deposit Designation PTA-3912."

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Claim 15 and dependent claims recite, “an avirulent, infectious chimeric porcine circovirus derived from a chimeric nucleic acid molecule of PCV1-2.” The term in question is “derived” because the structure of the derived products is indefinite. It is unclear what is retained from the source of derivation in the derived product. Without this knowledge, the metes and bounds of the claims cannot be determined. It is suggested that removal of reference to derivation be removed from the claims in order to overcome this rejection.

6. (*New Rejection*) Claims 4-10, 15, 16 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. One embodiment of the claims is drawn to a chimeric nucleic acid molecule (PCV1-2 construct) having at least 95% homology to the nucleotide sequence of SEQ ID NO: 2. This embodiment encompasses a large genus for which Applicant has not adequately demonstrated possession.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity (95%). There is not even identification of any particular portion of the structure that must be conserved. The specification

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does not provide examples of homologous nucleic acid molecules that are suitable for the invention. Without this knowledge, one of skill in the art would not be put in possession of the full scope of the claimed invention. SEQ ID NO: 2 has 1,773 nucleotides. If one were to substitute, delete or add any nucleotides along the 1,773 nucleotide sequence, the possibilities would be enormous. Applicant's disclosure fails to account for the large genus of polynucleotide molecules encompassed by the claim language, 95% homology. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived.

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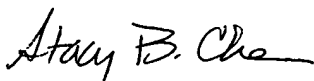
***Conclusion***

7. Claims 1-3 and 32 are free of the prior art of record. In view of the new grounds of rejection of the remaining elected claims, this Office action is non-final. Any inconvenience to Applicant is regretted. The following reference is cited of interest but not relied upon:

Audonnet *et al.* (US 6,943,152 B1, priority to June 10, 1999) teaches PCV DNA vaccines. The construct suggested is one plasmid encoding PCV-1 ORFs 1 and/or 2; and a separate plasmid encoding PCV-2 ORFs 1 and/or 2. While the plasmid may be administered concurrently, there is no suggestion to combine the two into a chimeric PCV1-2 construct.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Stacy B. Chen  
February 15, 2006